



Atty. Dkt. No. 036222-0212

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Albert R. Deisseroth and Lixin Zhang

Title: ADENOVIRAL VECTOR
VACCINE

Appl. No.: 10/534,605

Filing Date: 05/11/2005

Examiner:

Art Unit:

| | |
|--|--|
| CERTIFICATE OF MAILING | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below. | |
| ANITA PATEL | |
| (Printed Name) | |
| | |
| (Signature) | |
| JULY 19 2005 | |
| (Date of Deposit) | |

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment-IDS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date

July 19, 2005

FOLEY & LARDNER LLP

Customer Number: 30542

Telephone: (858) 847-6722

Facsimile: (858) 792-6773

By

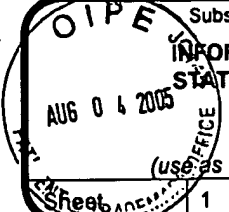
Barry Wilson

Barry S. Wilson

Attorney for Applicant

Registration No. 39,431

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | |
|---|--------------------------|----------------------|
|  Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) 1 of 9 | Complete if Known | |
| | Application Number | 10/534,605 |
| | Filing Date | May 11, 2005 |
| | First Named Inventor | Albert B. Deisseroth |
| | Group Art Unit | |
| | Examiner Name | |
| Attorney Docket Number | | 036222-0212 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| | A1 | 2003/0176377 | | Xiang, et al. | 09-18-2003 | |
| | A2 | 4,161,519 | | Talwar | 07-17-1979 | |
| | A3 | 4,608,251 | | Mia | 08-26-1986 | |
| | A4 | 5,658,785 | | Johnson, Phillip | 08/19/1997 | |
| | A5 | 5,849,522 | | Fleckenstein, et al. | 12/15/1998 | |
| | A6 | 5,849,876 | | Linsley, et al. | 12/15/1998 | |
| | A7 | 5,874,085 | | Mond, et al. | 02/23/1999 | |
| | A8 | 5,928,913 | | Efstathiou, et al. | 07/27/1999 | |
| | A9 | 5,962,406 | | Armitage, et al. | 10/05/1999 | |
| | A10 | 6,017,527 | | Maraskovsky, et al. | 01/25/2000 | |
| | A11 | 6,040,174 | | Imler, et al. | 03/21/2000 | |
| | A12 | 6,087,329 | | Armitage, et al. | 07/11/2000 | |
| | A13 | 6,110,744 | | Fang, et al. | 08/29/2000 | |
| | A14 | 6,133,029 | | Gruber, et al. | 10/17/2000 | |
| | A15 | 6,147,055 | | Hobart, et al. | 11/14/2000 | |
| | A16 | 6,218,140 | | Fleckenstein, et al. | 04/17/2001 | |
| | A17 | 6,224,870 | | Segal, Andrew | 05/01/2001 | |
| | A18 | 6,287,557 | | Bournsnel, at al. | 09/11/2001 | |
| | A19 | 6,290,972 | | Armitage, et al. | 09/18/2001 | |
| | A20 | 6,294,654 | | Bogen, et al. | 09/25/2001 | |
| | A21 | 6,440,944 | | Bruder, et al. | 08/27/2002 | |
| | A22 | 6,482,407 | | Soo Hoo, William | 11/19/2002 | |
| | A23 | 6,497,876 | | Maraskovsky, et al. | 12/24/2002 | |
| | A24 | 6,500,641 | | Chen, et al. | 12/31/2002 | |
| | A25 | 6,566,128 | | Graham, et al. | 05/20/2003 | |
| | A26 | 6,794,188 | | Barsov | 09-21-2004 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|-------------------------|---------------------|--|--|---|----------------|
| | | Office ³ | Number ⁴ | | | | |
| | A27 | | WO 2004/044176 | Deisseroth et al. | 05-27-2004 | | |
| | A28 | | WO 96/11279 | The Government of the United States of America | 04-18-1996 | | |
| | A29 | | WO 98/17799 | The Trustees of the University of Pennsylvania | 04-30-1998 | | |

Examiner Signature

/Phillip Gambel/

Date Considered

07/06/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|-------------|--------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/534,605 |
| | | Filing Date | May 11, 2005 |
| | | First Named Inventor | Albert B. Deisseroth |
| | | Group Art Unit | |
| Examiner Name | | | |
| Attorney Docket Number | 036222-0212 | | |
| Sheet | 2 | of | 9 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A30 | ALLISON and Byars, "Immunological Adjuvants and their mode of action." (in <u>Vaccines: New Approaches to Immunological Problems</u> , R. Ellis ed., Chapter 19), pp. 431-449. | |
| | A31 | ANDRIANIFAHANANA, et al., "Mucin (MUC) Gene Expression in Human Pancreatic Adenocarcinoma and Chronic Pancreatitis: A Potential Role of MUC4 as a Tumor Marker of Diagnostic Significance," <i>Clin Cancer Res.</i> 7:4033-4040 (2001) | |
| | A32 | ARAI, et al., "Design of the linkers which effectively separate domains of a bifunctional fusion protein," <i>Protein Engineering</i> , 14(8):529-532 (2001) | |
| | A33 | BARUCH, et al., "The Breast Cancer-associated MUC1 Gene Generates Both a Receptor and Its Cognate Binding Protein," <i>Cancer Res.</i> , 59:1552-1561 (1999) | |
| | A34 | BIÉCHE, et al., "A gene dosage effect is responsible for high overexpression of the MUC1 gene observed in human breast tumors," <i>Cancer Genet. Cytogenet.</i> 98:75-80 (1997) | |
| | A35 | Bell et al., "Dendritic cells." (in <u>Advances in Immunology</u> , edited by Frank J. Dixon, Academic Press, Volume 72), 255-324, 1999. | |
| | A36 | Broder et al., Recombinant adenovirus-transduced dendritic cell immunization in a murine model of central nervous system tumor <i>Neurosurg Focus</i> 9:1-8, 2000. | |
| | A37 | BYARS, et al., "Adjuvant formulation for use in vaccines to elicit both cell-mediated and humoral immunity," <i>Vaccine</i> 5:223-228 (1987) | |
| | A38 | CHEN, et al., Linkage of CD40L to a self-tumor antigen enhances the antitumor immune responses of dendritic cell-based treatment. <i>Cancer Immunology Immunother.</i> 51(6) :341-348, 2002 | |
| | A39 | CHOUDHURY, et al., Dendritic cells derived in vitro from acute myelogenous leukemia cells stimulate antologous, antileukemic T-cell responses. <i>Blood</i> , 93(3) : 780-786, 1999. | |
| | A40 | Crook et al., Continued expression of HPV-16 E7 protein is required for maintenance of the transformed phenotype of cells co-transformed by HPV-16 plus EJ-ras. <i>EMBO J.</i> 8: 513-519, 1989. | |
| | A41 | DAKAPPAGARI et al., "Chimeric multi-human epidermal growth factor receptor-2 B cell epitope peptide vaccine mediates superior antitumor responses," <i>J Immuno.</i> 170(8):4242-4253 (2003) | |

| | | | |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|--------------------|------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|--------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/534,605 |
| | | | | Filing Date | May 11, 2005 |
| | | | | First Named Inventor | Albert B. Deisseroth |
| | | | | Group Art Unit | |
| Examiner Name | | | | | |
| Sheet | 3 | of | 9 | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A42 | Dhodapkar, <i>et al.</i> Rapid generation of broad T-cell immunity in humans after a single injection of mature dendritic cells. <i>J Clin Invest.</i> 104: 173-180, 1999. | |
| | A43 | ECK and TURKA, Generation of protective immunity against an immunogenic carcinoma requires CD40/CD40L and B7/CD28 interactions but not CD4+ T cells. <i>Cancer Immunology Immunother.</i> 48:336-341, 1999. | |
| | A44 | ENGELMANN, et al., Identification and topology of variant sequences within individual repeat domains of the human epithelial tumor mucin MUC1. <i>J. Biol. Chem.</i> 276:27764-27769, 2001. | |
| | A45 | FILIBE, MI, "Mucins and gastrointestinal malignancy. A new approach to the interpretation of biopsies," <i>Acta Med Port</i> 1:351-365 (1979) | |
| | A46 | FILIBE, MI, "Mucins in the human gastrointestinal epithelium: a review," <i>Invest Cell Pathol</i> 2:195-216 (1979) | |
| | A47 | Fong L, <i>et al.</i> Dendritic cells injected via different routes induce immunity in cancer patients. <i>J Immunol.</i> 166: 4254-4259, 2001. | |
| | A48 | FREUND, "The mode of action of immunologic adjuvants," <i>Adv. Tuberc. Res.</i> 7:130-148 (1956) | |
| | A49 | GARCON et al., "Universal vaccine carrier. Liposomes that provide T-dependent help to weak antigens," <i>J. Immunol.</i> 146:3697 (1991) | |
| | A50 | GENDLER S.J. et al, "Molecular cloning and expression of human tumor-associated polymorphic epithelial mucin," <i>J. Biol. Chem.</i> 265:15286-15293 (1990) | |
| | A51 | GONG, et al., "Selection and characterization of MUC1-specific CD8+ cells from MUC1 transgenic mice immunized with dendritic-carcinoma fusion cells." <i>Immunology</i> , 101:316-324 (2000) | |
| | A52 | GREENLEE, et al., "Cancer statistics, 2000," <i>Cancer J.</i> 50:7-33 (2000) | |
| | A53 | Gunzer et al., Dendritic cells and tumor immunity. <i>Semin Immunol</i> 13:291-302, 2001. | |
| | A54 | GUY, et al. "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease," <i>Proc. Natl. Acad. Sci. USA</i> 89:10578-10582 (1992) | |

| | | | |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|--------------------|------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|---|--------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/534,605 |
| | | Filing Date | May 11, 2005 |
| | | First Named Inventor | Albert B. Deisseroth |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet | 4 | of | 9 |
| | | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A55 | HOLLINGSWORTH, et al., "Expression of MUC1, MUC2, MUC3, and MUC4 mucin mRNA in human pancreatic and intestinal tumor cell lines," <i>Int J Cancer</i> 57:198-203 (1994) | |
| | A56 | Hsu et al. Vaccination of patients with B-cell lymphoma using autologous antigen-pulsed dendritic cells. <i>Nat Med.</i> 2: 52-58, 1996. | |
| | A57 | JEANNON, et al. "Altered MUC1 and MUC2 glycoprotein expression in laryngeal cancer," <i>Otolaryngol Head Neck Surg.</i> 124:199-202 (2001) | |
| | A58 | JOHNSON, et al., "Characterization of a Nontoxic Monophosphoryl Lipid A," <i>Rev. Infect. Dis.</i> 9:S512 (1987) | |
| | A59 | KANEDA, "New Vector Innovation for Drug Delivery: Development of Fusigenic Non- Viral Particles," <i>Curr Drug Targets</i> 4(8):599-602 (2003) | |
| | A60 | KIM, et al., "Aberrant expression of MUC5AC and MUC6 gastric mucins and sialyl Tn antigen in intraepithelial neoplasms of the pancreas," <i>Gastroenterology</i> 123:1052-1060 (2002) | |
| | A61 | KONTANI, et al., "Modulation of MUC1 mucin as an escape mechanism of breast cancer cells from autologous cytotoxic T-lymphocytes," <i>Br. J. Cancer</i> 84:1258-1264 (2001) | |
| | A62 | Kusuhara et al., Killing of naive T cells by CD95L-transfected dendritic cells (DC): <i>In vivo</i> study using killer DC-DC hybrids and CD4(+) T cells from DO11.10 mice. <i>Eur J Immunol</i> 32:1035-1043, 2002. | |
| | A63 | Lamikanra et al., Regression of established human papillomavirus type 16 (HPV-16) immortalized tumors <i>in vivo</i> by vaccinia viruses expressing different forms of HPV-16 E7 correlates with enhanced CD8(+) T-cell responses that home to the tumor site. <i>J Virol</i> , 75: 9654-9664, 2001. | |
| | A64 | Larsson et al., A recombinant vaccinia virus based ELISPOT assay detects high frequencies of Pol-specific CD8 T cells in HIV-1-positive individuals. <i>AIDS</i> 13:767-777, 1999. | |
| | A65 | Liu et al., Codon Modified Human Papillomavirus Type 16 E7 DNA Vaccine Enhances Cytotoxic T-Lymphocyte Induction and Anti-tumor Activity. <i>Virology</i> 15: 301-343, 2002. | |

| | | | |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|--------------------|------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|---|--------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/534,605 |
| | | Filing Date | May 11, 2005 |
| | | First Named Inventor | Albert B. Deisseroth |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet | 5 | of | 9 |
| | | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|---|----------------|
| Exam iner Initial s* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A66 | Luft et al., IFN-alpha enhances CD40 ligand-mediated activation of immature monocyte-derived dendritic cells. <i>Int Immunol</i> 14:367-380, 2002 | |
| | A67 | Markowicz and Engleman, Granulocyte-macrophage colony-stimulating factor promotes differentiation and survival of human peripheral blood dendritic cells <i>in vitro</i> . <i>J Clin Invest.</i> 85: 955-961, 1990. | |
| | A68 | MOREIN, et al., "Iscom, a novel structure for antigenic presentation of membrane proteins from enveloped viruses," <i>Nature</i> 308:457 (1984) | |
| | A69 | MULLER, et al., "Single-step induction of mammary adenocarcinoma in transgenic mice bearing the activated c-neu oncogene," <i>Cell</i> 54(1):105-115 (1988) | |
| | A70 | Murphy GP, et al. Infusion of dendritic cells pulsed with HLA-A2-specific prostate-specific membrane antigen peptides: a phase II prostate cancer vaccine trial involving patients with hormone-refractory metastatic disease. <i>Prostate</i> 38: 73-78, 1999. | |
| | A71 | Nestle et al. Vaccination of melanoma patients with peptide- or tumor lysate-pulsed dendritic cells. <i>Nat Med.</i> 4: 328-332, 1998. | |
| | A72 | NGUYEN, et al., "Membrane-bound (MUC1) and secretory (MUC2, MUC3, and MUC4) mucin gene expression in human lung cancer," <i>Tumor Biol.</i> 17(3):176-192 (1996) | |

| | | | |
|-----------------------|------------------|--------------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|-----------------------|------------------|--------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|--------------------------|----------------------|------------------------|-------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete If Known | | | |
| | | Application Number | 10/534,605 | | |
| | | Filing Date | May 11, 2005 | | |
| | | First Named Inventor | Albert B. Deisseroth | | |
| | | Group Art Unit | | | |
| Examiner Name | | | | | |
| Sheet | 6 | of | 9 | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|--|----------------|
| Exam iner Initial s* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate); title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A73 | O'HAGAN, et al., "Biodegradable microparticles as controlled release antigen delivery systems," <i>Immunology</i> 73:239-242 (1991) | |
| | A74 | Paglia P, et al. Murine dendritic cells loaded <i>in vitro</i> with soluble protein prime cytotoxic T lymphocytes against tumor antigen <i>in vivo</i> (see comments). <i>J Exp Med</i> 183: 317-322, 1996. | |
| | A75 | Palucka and Banchereau, Dendritic cells: A link between innate and adaptive immunity. <i>J Clin Immunol.</i> 19:12-25, 1999. | |
| | A76 | REDMOND, et al., "Rotavirus particles function as immunological carriers for the delivery of peptides from infectious agents and endogenous proteins," <i>Mol. Immunol.</i> 28:269 (1991) | |
| | A77 | REGIMBALD, et al., "The breast mucin MUC1 as a novel adhesion ligand for endothelial intercellular adhesion molecule 1 in breast cancer," <i>Cancer Res.</i> 56:4244-4249 (1996) | |
| | A78 | REN, et al., "Protein Kinase C Regulates Function of the DF3/MUC1 Carcinoma Antigen in -Catenin Signaling*," <i>J. Biol. Chem.</i> 277:17616-17622 (2002) | |
| | A79 | RETZ, et al., "Differential mucin MUC7 gene expression in invasive bladder carcinoma in contrast to uniform MUC1 and MUC2 gene expression in both normal urothelium and bladder carcinoma," <i>Cancer Res.</i> 58:5662-5666 (1998) | |
| | A80 | Ribas et al., CD40 cross-linking bypasses the absolute requirement for CD4 T cells during immunization with melanoma antigen gene-modified dendritic cells. <i>Cancer Res.</i> 61:8787-8793, 2001. | |

| | | | |
|-----------------------|------------------|--------------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|-----------------------|------------------|--------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|---|--------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
| | | Application Number | 10/534,605 |
| | | Filing Date | May 11, 2005 |
| | | First Named Inventor | Albert B. Deisseroth |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet | 7 | of | 9 |
| | | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|--|----------------|
| Exam iner Initial s* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A81 | Rininsland et al., Granzyme B ELISPOT assay for ex vivo measurements of T cell immunity. J Immunol Methods 240:143-155, 2000. | |
| | A82 | ROWSE, et al., "Tolerance and immunity to MUC1 in a human MUC1 transgenic murine model," <i>Cancer Res.</i> 58:315 (1998) | |
| | A83 | Rudolf et al., Human dendritic cells are activated by chimeric human papillomavirus type-16 virus-like particles and induce epitope-specific human T cell responses <i>in vitro</i> . J Immunol. 166: 5917-5924, 2001 | |
| | A84 | Shortman K, and Caux C. Dendritic cell development: multiple pathways to nature's adjuvants Stem Cells 15:409-419, 1997 | |
| | A85 | Skov et al., IL-2 and IL-15 regulate CD154 expression on activated CD4 T cells J Immunol. 164:3500-3505, 2000. | |
| | A86 | Steinbrink et al., CD4(+) and CD8(+) anergic T cells induced by Interleukin-10-treated human dendritic cells display antigen-specific suppressor activity. Blood 99: 2468-2476, 2002. | |
| | A87 | TANG et al., "Multistep process through which adenoviral vector vaccine overcomes anergy to tumor-associated antigens." Blood, 104:2704-2713, 2004. | |
| | A88 | Timmerman and Levy, Dendritic cell vaccines for cancer immunotherapy. Annual Rev Med. 50: 507-529, 1999. | |

| | | | |
|-----------------------|------------------|--------------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|-----------------------|------------------|--------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|--|--|--|-------------------------------|----------------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Complete If Known | |
| | | | | Application Number | 10/534,605 |
| (use as many sheets as necessary) | | | | Filing Date | May 11, 2005 |
| | | | | First Named Inventor | Albert B. Deisseroth |
| | | | | Group Art Unit | |
| Sheet 8 of 9 | | | | Examiner Name | |
| | | | | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A89 | THOMAS, et al., "Non-viral gene therapy: polycation-mediated DNA delivery," <i>Appl Microbiol Biotechnol</i> 62(1):27-34 (2003) | |
| | A90 | WANG, et al., "Essential roles of tumor-derived helper T cell epitopes for an effective peptide-based tumor vaccine," <i>Cancer Immun.</i> 3:16 (2003) | |
| | A91 | XIANG, et al., "A dual-function DNA vaccine encoding carcinoembryonic antigen and CD40 ligand trimer induces T cell-mediated protective immunity against colon cancer in carcinoembryonic antigen-transgenic mice," <i>The Journal of Immunology</i> , 167:4560-4565 (2001) | |
| | A92 | YAMAMOTO M., et al., "Interaction of the DF3/MUC1 Breast Carcinoma-associated Antigen and -Catenin in Cell Adhesion," <i>J. Biol. Chem.</i> 272:12492-12494 (1997) | |
| | A93 | YANAGI, et al., "Immuno-gene therapy with adenoviruses expressing fms-like tyrosine kinase 3 ligand and CD40 ligand for mouse hepatoma cells in vivo," <i>International Journal of Oncology</i> 22:345-351 (2003) | |
| | A94 | YU, et al., "Overexpression of MUC5 genes is associated with early post-operativemetastasis in non-small-cell lung cancer," <i>Int. J. Cancer</i> 69:457-465 (1996) | |
| | A95 | ZHANG, et al., "An adenoviral vector cancer vaccine that delivers a tumor-associated antigen/CD40-ligand fusion protein to dendritic cells," <i>Proc. Natl. Acad. Sci (USA)</i> 100(25):15101 (2003) | |
| | A96 | ZHENG et al., "Induction of antitumor immunity via intratumoral tetra-costimulator protein transfer," <i>Cancer Research</i> 61:8127-8134 (2001) | |

| | | | |
|--------------------|------------------|-----------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|--------------------|------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|--------------------------|----------------------|------------------------|-------------|
| Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | Complete if Known | | | |
| | | Application Number | 10/534,605 | | |
| | | Filing Date | May 11, 2005 | | |
| | | First Named Inventor | Albert B. Deisseroth | | |
| | | Group Art Unit | | | |
| Examiner Name | | | | | |
| Sheet | 9 | of | 9 | Attorney Docket Number | 036222-0212 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--------------------------|--|----------------|
| Exam Iner Initial s* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| | A97 | Zitvogel L, <i>et al.</i> Therapy of murine tumors with tumor peptide-pulsed dendritic cells: dependence on T cells, B7 co-stimulation, and T helper cell 1-associated cytokines. J Exp Med. 183: 87-97, 1996. | |
| | A98 | ZRIHAN-LICHT S., et al., "Tyrosine phosphorylation of the MUC1 breast cancer membrane proteins. Cytokine receptor-like molecules," <i>FEBS Lett.</i> 356:130-136 (1994) | |
| | A99 | Zwaveling et al., Established human papillomavirus type 16-expressing tumors are effectively eradicated following vaccination with long peptides. J Immunol, 169:350-358, 2002. | |

| | | | |
|-----------------------|------------------|--------------------|------------|
| Examiner Signature | /Phillip Gambel/ | Date Considered | 07/06/2010 |
|-----------------------|------------------|--------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.G./